

#### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: David R. Milich et al.

Serial No.:

10/630,070

Group No.:

Filed:

07/30/2003

Examiner:

Entitled:

Rodent Hepatitis B Virus Core Proteins As Vaccine

Platforms And Methods Of Use Thereof

# INFORMATION DISCLOSURE STATEMENT TRANSMITTAL

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

#### CERTIFICATE OF MAILING UNDER 37 C.F.R. § 1.8(a)(1)(i)(A)

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Dated: October 29

Cliff Cannon-Cin

Sir or Madam:

Enclosed please find an Information Disclosure Statement and Form PTO-1449, including copies of the references contained thereon, for filing in the U.S. Patent and Trademark Office.

The Commissioner is hereby authorized to charge any additional fee or credit overpayment to our Deposit Account No. 08-1290. An originally executed duplicate of this transmittal is enclosed for this purpose.

Dated: 10 - 29-2003

Registration No. 43,655

MEDLEN & CARROLL, LLP 101 Howard Street, Suite 350 San Francisco, California 94105 415/904-6500



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Cliff Cannon-Cin

### Sir or Madam:

The following citations and information may be material to the examination of the above-identified application, and are therefore submitted in compliance with the duty of disclosure defined in 37 C.F.R. §§ 1.56 and 1.97. The Examiner is requested to make these citations and information of official record in this application.

The following patents are referred to in the body of the specification:

- WO 02/13765 published 12/21/02;
- U.S. Patent No. 4,683,195 issued 7/28/87 to Mullis et al.
- U.S. Patent No. 4,683,202 issued 7/28/87 to Mullis; and
- U.S. Patent No. 4,965,188 issued 10/23/90 to Mullis et al.

The following printed publications are referred to in the body of the specification:

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Applicants have become aware of the following information and citations which may be material to the examination of the above-identified application:

The inventors collaborated, more than one year before filing the instant application, with Dr. Darrell Peterson, at Virginia Commonwealth University, in the reduction to practice of one or more embodiments of the claimed invention. This collaboration is not "public use" under 35 U.S.C. §102(b) because it was not for profit, but rather for scientific research. Also, this collaboration was not "public" because it was performed under a grant awarded by the National Institutes of Health (NIH), on which Dr. Peterson and co-

<sup>&</sup>lt;sup>1</sup> Electric Strorage Battery Co. v. Shimadzu, 307 US 5, 41 USPQ 155 (1939) ( "[A] single use for profit, not purposely hidden" is public use).

inventor Dr. Milich were named as co-investigators. Thus, the collaboration occured with an understanding and expectation of confidentiality.<sup>2</sup>

- U.S. Patent No. 6,602,705 issued 8/5/03 to Barnett et al.;
- U.S. Patent No. 6,406,705 issued 6/18/02 to Davis et al.;
- U.S. Patent No. 6,231,864 issued May 15, 2001 to Birkett;
- U.S. Patent No. 4,599,230 issued July 8, 1986 to Milich et al.;
- U.S. Patent No. 4,599,231 issued July 8, 1986 to Milich et al.;
- U.S. Patent No. 4,683,136 issued July 8, 1987 to Milich et al.;
- U.S. Patent No. 5,726,011 issued March 10, 1998 to Milich et al.;
- U.S. Patent No. 4,818,527 issued April 4, 1989 to Thornton et al.;
- U.S. Patent No. 4,882,145 issued November 21, 1989 to Thornton et al.;
- U.S. Patent No. 5,143,726 issued September 1, 1992 to Thornton et al.;
- WO 01/98333 A2 published 12/27/01;
- Genbank Accession No. NP\_671816 printed 8/3/93;
- Genbank Accession No. NKVLC printed 7/16/99;
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<sup>&</sup>lt;sup>2</sup> Xerox Corp. v. 3Com Corp., 49 USPQ2d 1772 (DC WNY, 9/29/98) (A disclosure is insufficient to constitute a "public use" under 102(b) if it is made with an understanding and expectation of confidentiality, even in the absence of an express confidentiality agreement).

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   July 24, 2003 as Publication No. 20030138769, and entitled "Immunogenic
   HBc chimeric particles having enhanced stability," and
- Brown *et al.*, U.S. patent publication No. US 20030175296 published Sept. 18, 2003, and entitled "Chimaeric hepadnavirus core antigen proteins."

This Information Disclosure Statement under 37 C.F.R. §§ 1.56 and 1.97 is not to be construed as a representation that a search has been made, that additional information material to the examination of this application does not exist, or that any one or more of these citations constitutes prior art.

Signed on behalf of:

Dated: 10-29-2003

Maha-A. Hamdan Registration No. 43,655

MEDLEN & CARROLL, LLP 101 Howard Street, Suite 305 San Francisco, California 94105 415/904-6500 FORM PTO-144 (Modified)

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Attorney Docket No.: VACCINE-07083

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use Several Sheets If Necessary)

Applicant: David R. Milich et al.

(37 CFR § 1.98(b))				Filing Date: 07/30/2003		Group Art Unit:			
				U.S. PATENT DOC	UMENTS				
Examiner Initials	Cite No.	Serial / Patent Number	Issue Date	Applica	ant / Patentee	Class	Subclass	Filing	Date
	1	4,683,195	7/28/87	Mullis et al.					<u></u>
	2	4,683,202	7/28/87		Mullis				
	3	4,965,188	10/23/90	Mu	llis <i>et al</i> .				
	4	6,602,705	8/5/03	Bar	nett et al.				
	5	6,406,705	6/18/02	Davis et al.					
	6	6,231,864	5/15/01		Birkett				
	7	4,599,230	7/8/86	Mil	ich et al.				
	8	4,599,231	7/8/86	Mil	ich et al.				
	9	4,683,136	7/8/87	Mil	ich et al.				
	10	5,726,011	3/10/98	Milich et al.					
	11	4,818,527	4/4/89	Thor	nton et al.				
	12	4,882,145	11/21/89	Thor	nton <i>et al</i> .				
	13	5,143,726	9/1/92	Thor	nton <i>et al</i> .				
		FC	REIGN PATENTS C	R PUBLISHED FOR	REIGN PATENT APPL	ICATIONS		•	
		Document Davis Company						lation	
		Number P	Publication Date	Country / Patent Office	Class	Subclass	Yes	No	
	14	WO 02/13765	12/21/02		PCT				
	15	WO 01/98333 A2	12/27/01		PCT				
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U.S. Department of Commerce Patent and Trademark Office

Attorney Docket No.: VACCINE-07083

Serial No.: 10/630,070

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Applicant: David R. Milich et al.

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Serial No.: 10/630,070

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Applicant: David R. Milich et al.

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Filing Date: 07/30/2003

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FORM PTO-144 (Modified)

U.S. Department of Commerce Patent and Trademark Office

Attorney Docket No.: VACCINE-07083

Serial No.: 10/630,070

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